97 95
~~79~~. (New) The insert of claim ~~77~~, wherein said insert is configured in the shape of a cross.

98 95
~~80~~. (New) The insert of claim ~~77~~, wherein said insert is configured in the shape of a boomerang.

99
~~81~~. (New) An intracorneal refractive correction insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible polymer and being adapted for implantation within a human cornea, said insert further comprising a first elongated portion and a second elongated portion extending therefrom in a different direction, one of said first and said second portions being configured for radial insertion in the cornea of a human eye.

100 99
~~82~~. (New) The insert of claim ~~81~~, wherein said first elongated portion has said second and a third elongated portion extending therefrom.

101 100
~~83~~. (New) The insert of claim ~~82~~, wherein said insert is configured in the shape of an anchor.

102 100
~~84~~. (New) The insert of claim ~~82~~, wherein said insert is configured in the shape of a boomerang.

103 100
~~85~~. (New) The insert of claim ~~82~~, wherein said insert is configured in the shape of a cross.

II. REMARKS

Claims 50 to 67 are pending in the subject application. By this Amendment, claims 68 to 85 (corresponding to the subject matter of previously pending claims 1 to 5) have been added. Support for the addition of new claims 68 to 85 can be found throughout the specification and claims as originally filed. Thus, the addition of new claims 68 to 85 does not raise an issue of new matter and entry thereof is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

In view of the preceding amendments and the following remarks, Applicants respectfully request reconsideration and withdrawal of the outstanding objections and rejections.

Status of the Claims

Claims 1 to 5, 11 to 13, 22 to 35 and 41 to 49 were pending in the subject application. These claims were canceled in an amendment filed January 7, 2002, and new claims 50 to 67 were added. In the first examination of these claims (Office Action issued June 20, 2002 (Paper No. 32), the claims were rejected as being directed to a non-elected invention and the response as a whole was deemed non-responsive. The amended claims were rejected and the Office Action issued June 20, 2002 was made final. In a paper mailed July 29, 2002, the Office vacated the June 20, 2002 final Office Action and requested Applicants respond to the rejections set forth previously, and as repeated in the action of June 20, 2002.

New claims 68 to 85 have been added which correspond to the claims of the elected invention, i.e., claims 1 to 5, 11 to 13, 22 to 35 and 41 to 49. After entry of the new claims, claims 50 to 85 are pending in the subject application.

35 U.S.C. § 112, Second Paragraph

The claims were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have rephrased the claimed subject matter in the newly added claims in a sincere attempt to overcome the grounds for rejection. For example, the element that at least one of the insert's components extends in a meridional direction corrects the antecedent basis for "its centroidinal axis". In view of these amendments, reconsideration and withdrawal of the rejections is respectfully requested.

35 U.S.C. §102 (b)

The claims were rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Herrick, U.S. Patent No. 4,781,187 ("Herrick"). In particular, the Office pointed to the subject matter of prior claims 1, 2, 5, 11 and 30 to 35 as allegedly anticipated by Herrick.

Prior claims 1 and 41 to 46 also were rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Gonchar et al. ("Interlayer Refraction Tunnel Keratoplasty in Correcting Myopia and Asigmatism"). In particular, the Office points to claim 41 (now claim 80) as allegedly anticipated by page 4, line 16 of the English abstract.

Prior claims 1, 2, 5, 11, 22, 23, 25 and 26 were rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Civerchia U.S. Patent No. 4,781,187 ("Civerchia"). In particular, the Office points to prior claim 1 as being allegedly anticipated by Figures 14 and 17 (Figure 4; column 6, lines 20-21; column 18, lines 9 to 12) which is alleged to show a structure that allegedly possess a radius of curvature along a centroidinal axis of at least 5.0 mm. Regarding prior claim 23, the Office alleged that was clearly anticipated at column 13, lines 28 through 35. Regarding claim 26, the Office alleged that it was clearly anticipated at column 12, lines 9 to 13.

Applicants respectfully traverse. New claims 68 to 85 have been drafted in a sincere effort to overcome the grounds for rejection of the claims as previously presented.

New claim 85 corresponds to prior claim 1. New claim 85 recites that the insert is comprised of a "physiologically compatible polymer" and that intracorneal insert for introduction into the cornea of a human eye, comprised of a physiologically compatible material and adapted for implantation into a human cornea.

Herrick describes an insert which is comprised of donor cornea tissue. *See* Herrick, column 1, lines 38 to 42 and column 2, lines 16 to 27. Herrick also discloses a method of radial keratotomy using thin piece (s) of donor corneal tissue as its insert (s). *See* claims 1 to 6. In contrast, Applicants do not claim the use of donor corneal tissue in the insert.

Gonchar, et al., like Herrick discloses the use of donated corneal tissue to create the implants. *See* page 2, paragraph beginning at line 9 and Figure 2.

The newly presented claims also recite that the intracorneal insert possess a radius of curvature along a centroidinal axis of at least 5.0 mm, and said component also extends in a "meridional direction thereby to effect refractive correction".

While the Office alleges that Civerchia discloses an insert with a radius of curvature along a centroidinal axis of at least 5.0 mm, it does not disclose a component which extends in a meridional direction.

Thus, the newly added claims are not anticipated by the cited references.

Claims 1, 2, 5, 11, 12 and 27 through 35 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Lindstrom US 4,799,931 ("Lindstrom"). However, the Office did not set forth the grounds for rejection. For this reason, Applicants are unable to reply.

In view of the addition of the new claims and the preceding remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102 (b).

35 U.S.C. §103 (a)

Prior claims 3, 4, and 41 to 49 stand rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Herrick U.S. Patent No. 4,781,187 ("Herrick"). The Office alleged that with respect to prior claims 3 and 4 (now claims 70 and 71, respectively), the radius of curvature would have been immediately obvious from the intended use of the device, as best illustrated by Figures 3, 4, 7, and 9. Further the Office alleged that with respect to prior claim 41, while Herrick specifies dimensions "on the order of a length of 3.5 to 4.0 millimeters", lengths of less than 2.5 millimeters would have been obvious in order to accommodate experimentation or practice on small animals or to minimize the length of the corneal incisions.

The Office also alleged that prior claims 3, 4 , and 47 to 49 were rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Gonchar, et al. ("Interlayer Refraction Tunnel Keratoplasty in Correcting Myopia and Asigmatism"). The Office alleged that a radius of curvature within the range set forth in claim 4 (now claim 71) would have been immediately obvious from the purpose of the alloimplants as described in Figure 3 of Gonchar, et al. The

Office further alleged that with respect to prior claim 49, an implant having the length of 2.0 mm or less would have been obvious in order to accommodate a variety of eye sizes and refractive disorders.

Prior claims 3, 4, 24, and 41 through 49 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Civerchia US 5,213,720 ("Civerchia"). The Office alleged that the particular radius of curvature for claims 3 and 4 would have been immediately obvious from the anatomy described in Figure 4 of Civerchia.

Prior claims 3, 4 and 13 were rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Lindstrom US 4,799,931 ("Lindstrom"). The Office alleged that a value within the range set forth in prior claim 4 would have been obvious for reasons similar to those above (Applicants assume Office refers to arguments within this section for Herrick, Gonchar, et al. and Civerchia). The particular material recited in prior claim 13 is alleged to have been obvious from the list of materials at column 2, lines 9 through 11.

Applicants respectfully traverse.

New claims 68 to 85 have been drafted in a sincere effort to overcome the grounds for rejection of the prior, now cancelled claims. The new claims are directed to an insert that is comprised of a "physiologically compatible polymer" rather than "physiologically compatible material." New claim 71 recites an insert comprised of a physiologically compatible polymer having at least one elongated portion having a radius of curvature, measured along the centroidinal axis, of between 6.0 and 9.0 mm, wherein one component of the insert extends in a meridional direction comprised of a "physiologically compatible polymer" rather than as a "physiologically compaticble material" which could include a corneal tissue implant.

New claim 68 claims an insert having a radius of curvature along a centroidinal axis of at least 5.0 mm which extends in a "meridional direction thereby to effect refractive correction". Therefore, without confirming the Office's allegation that the radius of curvature for claims 3 and 4 would be obvious from the anatomy described in Figure 4 of Civerchia, Applicants have clearly claimed an invention wherein the insert not only has a radius of at least 5.0 mm, but also extends in a meridional direction not obvious in Figure 4 of Civerchia.

Accordingly, new claims 68 through 85 are not rendered obvious by the cited references and Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

Change of Firm Name

Effective July 1, 2002, the firms of McCutchen, Doyle, Brown & Enersen, LLP and Bingham Dana LLP merged to become Bingham McCutchen LLP.

III. CONCLUSION

If a telephone interview would advance prosecution of the subject application, the Examiner is invited to telephone the undersigned at the number provided below. In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1189**, referencing billing reference **23915-7316.** However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: October 31, 2002

By: _____
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at page 11, line 24 has been amended as follows:

Figure 4B shows an insert (222) having both a significant meridional length component (224) [and a significant meridional length component (224)] and a significant width or circumferential component (226). The ratio of the length of the meridional length component (224) to the width or circumferential component (226) in the variation shown in Figure 4B is about 1.0. Its general positioning to the corneal meridian (206) is also depicted in the Figure.

Paragraph beginning at page 14, line 10 has been amended as follows:

Further, the typical width of the individual inserts discussed above is often between 0.2 mm and 2.0 mm. The typical thickness is often between 0.15 mm and 0.5 mm. In addition to the width and thickness of the insert tapering at one or both ends, the thickness of the insert may optionally vary from one end to the other end of the insert (*e.g.*, along the centroidal length of the insert) to provide for a desired change in corneal curvature at the location of the insert. The centroidal length of the insert (*i.e.*, the length of the insert measured along the centroidal axis of the insert) is contemplated to rarely exceed[s] 3.0 mm. Preferably, the insert has a centroidal length which is less than or equal to 2.5 mm, and more preferably less than 2.0 mm. When the centroidal length is determined for an insert configuration other than the simple configuration shown in Figure 4A (*e.g.*, such as the insert shown in Figure[s] 4B), the centroidal length corresponds to the length of the radially arcuate portion measured along the centroidal axis of that portion. As another example (*e.g.*, the insert of Figure 4C), this length corresponds to the length of the generally radially extending leg (*e.g.*, the non-circumferentially extending portion) measured along its centroidal axis. These parameters (along with certain other variables such as the cross-sectional shape of the device and its constituent polymers and stiffness) determine in large part, the level of correction achievable by use of a selected insert.

Paragraph beginning at page 17, line 21 has been amended as follows:

Additionally, the polymeric material making up the insert may be one or more low modulus polymers, e.g., those having a modulus of elasticity below about 3.5 kpsi, more preferably between 1 psi and 1 kpsi, and most preferably between 1 psi and 500 psi, which are physiologically compatible with the eye. Most polymeric materials used in soft contact lenses are suitable materials for making up the inserts of this invention. The class includes physiologically compatible elastomers and such polymers, typically crosslinked, as polyhydroxyethylmethylacrylate (poly-HEMA) or polyvinylpyrrolidone (PVP), polyethylene oxide, or polyacrylates, polyacrylic acid and its derivatives, their copolymers and interpolymers, and the like as well as biologic polymers such as crosslinked dextran, crosslinked heparin, or hyaluronic acid. Acrylic polymers having a low T_g are also suitable.

Paragraph beginning at page 29, line 10 has been amended as follows:

Alternatively, multiple corneal markers can be used to form the incision mark, the clockwise and counterclockwise circumferential channel marks, and the radial pocket marks which aid the surgeon during surgery. For example, two corneal markers [and] can be used to form the desired marks. One corneal marker may have an incision marker, clockwise and counterclockwise channel markers, and a reticule or sight to enable the corneal marker to be aligned to the center mark (360) of the patient's cornea. The second marker may have radial pocket markers and a reticule or sight. Each corneal marker is individually aligned with the center mark (360) and pressed against the patient's cornea to form the desired marks. The combined incision/circumferential channel markers [is] are usually pressed against the cornea before any vacuum centering guide is placed thereon so that the surgeon can easily make the initial inci[s]sion into the cornea. After the vacuum centering guide is placed on the cornea, the surgeon inserts the second corneal marker into the vacuum guide and presses it against the patient's cornea to [from] form radial marks on the cornea to guide surgery.

In the Claims:

68. (Amended) An intracorneal insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible polymer and further comprising at least one elongated portion having a component with a radius of curvature, measured along the

centroidinal axis of the insert, greater than 5.0 mm, wherein the insert is adapted for implantation within a human cornea with said component extending in a meridional direction thereby to effect refractive correction.

69. (New) The insert of claim 68, wherein said radius of curvature is at least 5.5 mm.

70. (New) The insert of claim 68, wherein said radius of curvature is between 6.0 and 9.0 mm.

71. (New) The insert of claim 68, wherein said radius of curvature is between 7.0 and 8.0 mm.

72. (New) The insert of claim 68, wherein said meridional component has a radius of curvature approximating a human corneal curvature when placed in the eye.

73. (New) The insert of claim 68, having a centroidinal length of less than 3.0 mm.

74. (New) The insert of claim 73, wherein said centroidinal length is less than or equal to 2.5 mm.

75. (New) The insert of claim 73, wherein said centroidinal length is less than or equal 2.0 mm.

76. (New) The insert of claim 68, wherein said elongated portion extends only in a single direction.

77. (New) The insert of claim 68, including at least two elongated portions extending in different directions.

78. (New) The insert of claim 77, wherein said insert is configured in the shape of an anchor.

79. (New) The insert of claim 77, wherein said insert is configured in the shape of a cross.

80. (New) The insert of claim 77, wherein said insert is configured in the shape of a boomerang.

81. (New) An intracorneal refractive correction insert for introduction into the cornea of a human eye, said insert comprising a physiologically compatible polymer and being adapted for implantation within a human cornea, said insert further comprising a first elongated portion and a second elongated portion extending therefrom in a different direction, one of said first and said second portions being configured for radial insertion in the cornea of a human eye.

82. (New) The insert of claim 81, wherein said first elongated portion has said second and a third elongated portion extending therefrom.

83. (New) The insert of claim 82, wherein said insert is configured in the shape of an anchor.

84. (New) The insert of claim 82, wherein said insert is configured in the shape of a boomerang.

85. (New) The insert of claim 82, wherein said insert is configured in the shape of a cross.